K121657

OCT 2 3 2012

SECTION 5 – 510(k) Summary for Radiation Therapy Beam-Shaping Aperture and Range Compensator

1. Submission Sponsor

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2. Submission Correspondent

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3. Date Prepared

25 May 2012

4. Device Name

Trade/Proprietary Name: Proton radiation therapy beam-shaping aperture and range compensator

Common/Usual Name: Proton radiation therapy beam-shaping aperture and range compensator

Classification Name: Radiation Therapy Beam-Shaping Block

Classification Regulation: 892.5710

Classification Panel: Radiology

Product Code: IXI
Device Class: II

5. Predicate Devices

1. . Decimal Aperture K071077
2. . Decimal Range Compensator K071078

6. Device Description

Proton Systems manufactures radiation therapy beam-shaping apertures and range compensators to customer patient-specific specifications.

In proton therapy for cancer, a proton beam is aimed at the cancerous tissue using a large "snout". The snout is rotated around the patient using a large, three-story gantry. While the patient lies on a treatment table, the gantry rotates around and points the snout at predetermined positions to maximize efficiency and dose delivery to the tumor volume. Each gantry angle, or port, requires two custom-made, beam-modifying patient-specific devices: an **aperture** and a **range compensator**.

The aperture is inserted into the gantry's snout to shape and focus the proton beam as it exits the gantry en route to the targeted area. The aperture is made of brass 360 with a 2D pattern / hole cut out of it, which defines the area that is to be treated with the proton beam. The range compensator is made of acrylic or wax and controls the depth at which the proton beam energy is delivered. The custom shape and design for apertures and range compensators are generated out of the hospital's treatment planning software and are unique to each patient and each gantry angle (most patients will have two to three different gantry angles).

7. Intended Use

Proton Systems' proton radiation therapy beam-shaping aperture and range compensator manufacturing service manufactures the solid apertures and range compensators for intensity modulation of external beam proton radiation therapy. The apertures and range compensators are designed by the customer's treatment planning system to block radiation from hitting critical structures and healthy tissue while guiding the radiation to the targeted area.

8. Technological Characteristics and Substantial Equivalence

The following Table 5.1 compares the Proton Systems proton radiation therapy beam-shaping aperture and range compensator to the Predicate Devices with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5.1
Substantial Equivalence Comparison

	Proton Systems, Inc.	**. Decimal, Inc.**
Trade Name	Proton radiation therapy beam-shaping aperture and range compensator	. Decimal Aperture . Decimal Range Compensator
Product Code	IXI	IXI
Regulation Number	892.5710	892.5710
Regulation Name	Radiation Therapy Beam-Shaping Block	Radiation Therapy Beam-Shaping Block
510(k) Numbers	TBD	K071077 - Dot Decimal Aperture, K071078 - Dot Decimal Range Compensator
Indications for Use	Proton Systems' proton radiation therapy beam-shaping aperture and range compensator manufacturing service manufactures the solid apertures and range compensators for intensity modulation of external beam proton radiation therapy. The apertures and range compensators are designed by the customer's treatment	.decimal's Aperture manufacturing service manufactures the solid apertures for intensity modulation of external beam proton radiation therapy. The apertures are designed by the customer's treatment planning system to block radiation from hitting critical structures and healthy tissue while guiding the radiation to the targeted area.

Table 5.1 **Substantial Equivalence Comparison**		
	Proton Systems, Inc.	**. Decimal, Inc.**
	planning system to block radiation from hitting critical structures and healthy tissue while guiding the radiation to the targeted area.	.decimal's Range Compensator manufacturing service manufactures the solid Range Compensators for intensity modulation of external beam proton radiation therapy. The Range Compensator are designed by the customer's treatment planning system to block radiation from hitting critical structures and healthy tissue while guiding the radiation to the targeted area.
Type of Radiation Product is Intended for	Proton Beam	Proton Beam
Device Material	Aperture – Brass 360 Range Compensator – Machinable Wax or Acrylic	Aperture – Brass 360 Range Compensator – Machinable Wax or Acrylic
Device Sizes	30 x 40 cm 100 cm 180 cm 250 cm	30 x 40 cm 100 cm 180 cm 250 cm
Single Use	No	No
Supplied Sterile	No	No
Requires Sterilization	No	No

9. Non-Clinical Testing

Testing to support this submission can be found in Appendix 5 – Performance Testing.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use are equivalent to the predicate device.

11. Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is as safe and effective as the predicate device, and that the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the **proton radiation therapy beam-shaping aperture and range compensator** manufactured by Proton Systems and the predicate devices listed are insignificant and do not raise any questions regarding its safety and effectiveness. The subject device, as designed and manufactured, is as safe and effective as the predicate devices for their intended application; that is, as a radiation therapy beam-shaping block, and therefore is determined to be substantially equivalent to the referenced predicate devices in the context of that application.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT 23 2012

Proton Systems
% Mr. Mike Begala
Senior Consultant
Emego Group, Inc.
611 West 5th Street, Third Floor
AUSTIN TX 78701

Re: K121657
Trade/Device Name: Radiation Therapy Aperture and Range Compensator
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 12, 2012
Received: September 12, 2012

Dear Mr. Begala:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K121657

Device Name

Radiation Therapy Aperture and Range Compensator

Indications for Use

Proton Systems' proton radiation therapy beam-shaping aperture and range compensator manufacturing service manufactures the solid apertures and range compensators for intensity modulation of external beam proton radiation therapy. The apertures and range compensators are designed by the customer's treatment planning system to block radiation from hitting critical structures and healthy tissue while guiding the radiation to the targeted area.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) K121657